

a present invention spinal nucleus implant 39, with a soft, high water content core 41 and an outer jacket with high crystalline polymer content 43. At their interface 45, an optional structural support or transition layer may be included.

FIG. 12 has a present invention spinal nucleus implant 51 with a core 53 and a jacket 55 and further includes structural support elements 57a in the core and 57b in the jacket.

FIG. 13 shows a partially cut present invention spinal nucleus implant sphere 61, cut along line AB. It has a center 63 with a low polymer content and a high water content with a gradient increasing in polymer content and decreasing in water content toward outer layer 69. For example, center 63 may contain ten percent polymer and ninety percent water and layer 65 may contain eighty percent of polymer and twenty percent water and layer 67 may contain thirty percent polymer and seventy percent water and outer surface 69 may contain even more water with a lubricious, negatively charged surface.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

What is claimed is:

1. A spinal nucleus implant for replacement of at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrate to restore function of said spinal disc and related vertebral joint, and implantable into the cavity created by said removal of nucleus pulposus tissue, which comprises:

A swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said biomimetic plastic having an inherent shape in which it has a relaxed polymer network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, said anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

2. The spinal nucleus implant of claim 1 wherein said implant is anisotropically deformable in its said indwelling shape having preferred deformability in a vertical plane and suppressed deformability in horizontal planes under compression in the vertical plane.

3. The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic is at least partially hydrated in its insertion xerogel state.

4. The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic has been formed in a physiologically safe form by being plasticized with a non-toxic liquid in its insertion xerogel state.

5. The spinal nucleus implant of claim 4 wherein said non-toxic liquid is present at a concentration less than 50% by weight of the plasticized anisotropically swellable, biomimetic plastic.

6. The spinal nucleus implant according to claim 3 wherein said non-toxic liquid is selected from the group

consisting of glycerol, glycerol monoacetate, glycerol diacetate, glycerylformal, dimethyl sulfoxide, water and mixtures thereof.

7. The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic is a dehydrated anisotropically swellable plastic wherein both said hydrophobic phase and said hydrophilic phase each have hydrophobic and hydrophilic aspects and said hydrophobic phase is a less hydrophilic phase having higher content of hydrophobic groups and said hydrophilic phase is a less hydrophobic phase having higher content of hydrophilic groups, relative to one another.

8. The spinal nucleus implant according to claim 7 wherein said anisotropically swellable, biomimetic plastic comprises non-degradable polymer with a carbon-carbon backbone.

9. The spinal nucleus implant according to claim 7 wherein said less hydrophilic phase is a crystalline phase containing nitrile groups.

10. The spinal nucleus implant according to claim 7 wherein said hydrophilic phase has hydrophilic groups which are selected from a group consisting of hydroxyl, carboxyl, carboxylate, amide, N-substituted amide, amidine and N-substituted amidine.

11. The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has water content more than 70% by weight in said state of fully hydration by deionized water.

12. The spinal nucleus implant according to claim 11 wherein said swellable, biomimetic plastic has water content more than 95% by weight in said state of full hydration.

13. The spinal nucleus implant according to claim 1 wherein said more hydrophilic phase is substantially discrete hydrophilic domains dispersed in a substantially continuous less hydrophilic domain.

14. The spinal nucleus implant according to claim 1 wherein both the hydrophilic phase and the hydrophobic phase are substantially continuous hydrophilic domains and hydrophobic domains forming an interpenetrating network.

15. The spinal nucleus implant according to claim 1 wherein said hydrophobic phase contains crystalline polymer phase detectable by x-ray diffraction.

16. The spinal nucleus implant according to claim 7 wherein said more hydrophobic phase is substantially discrete crystalline domains dispersed in a substantially continuous more hydrophilic domain.

17. The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has hydrophilic lubricious surface.

18. The spinal nucleus implant according to claim 17 wherein said surface is formed in a gradient manner with increasing carboxylic groups from the center of said implant towards its outer surface.

19. The spinal nucleus implant according to claim 1 wherein said implantable device has at least the two following structural components:

(a) an inner core from said swellable plastic; and,

(b) an outer jacket that is surrounding said core and made from said swellable plastic which is, in its fully hydrated state, less swellable than said inner core.

20. The spinal nucleus implant according to claim 1 including at least one reinforcing element from a substantially non-swellable material embedded in said swellable, biomimetic plastic.

21. The spinal nucleus implant according to claim 19 and further including at least one reinforcing element from a substantially non-swellable material embedded in said

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swellable, biomimetic plastic wherein said at least one reinforcing element is located between said jacket and said core.

22. The spinal nucleus implant according to claim 20 wherein said at least one reinforcing element is made from an implantable material selected from the group consisting of metal, metal alloys, carbon, ceramics, polymer and combinations thereof.

23. The spinal nucleus implant according to claim 22 wherein said polymer is selected from a group consisting of acrylic polymer, methacrylic polymer, polyester, polyurethane, polyurea, polyolefin, halogenated polyolefin, polysaccharide, vinylic polymer, polyphosphazene and polysiloxane.

24. The spinal nucleus implant according to claim 19 wherein said inner core is adherent to and connected to said outer jacket.

25. The spinal nucleus implant according to claim 20 wherein said reinforcing element is more deformable in axial direction than in lateral direction under axial stress.

26. The spinal nucleus implant according to claim 20 wherein said reinforcing element has a general shape selected from the group consisting of helix, ring, ellipsoid, cylinder and bellows.

27. A surgical implant procedure for replacing at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrae to restore function of said spinal disc and related vertebral joint, which comprises:

- a.) creating a spinal nucleus implant in the form of an anisotropically swellable, biomimetic xerogel plastic, having a two phase structure with a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said xerogel plastic being capable of anisotropic expansion by rehydration into an inherent shape in which it has a relaxed polymer network in a state of full hydration, and being capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state said anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and minimal swelling or suppressed swelling in horizontal planes;
- b.) surgically removing at least a portion of nucleus pulposus tissue from a spinal disc of a living vertebrae to create a cavity; and,
- c.) implanting said spinal nucleus implant into said nucleus pulposus cavity in an at least partially hydrated state.

28. The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated

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state, has volume substantially larger than volume of said cavity vacated by the removal of nucleus pulposus tissue.

29. The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated state, has a cross-section area substantially equivalent to the cross-section area of said cavity vacated by the removal of nucleus pulposus tissue, and height substantially larger than the height of said cavity, the "height" being the dimension substantial parallel with the spinal axis and "cross-section area" being the area lateral to the spinal axis.

30. The surgical implant procedure according to claim 27 wherein said xerogel plastic swells in situ substantially more in the direction of the spinal axis than in lateral direction.

31. The surgical implant procedure according to claim 27 wherein said xerogel plastic is implanted in an anisotropically dehydrated state in which its volume is less than 50% of the volume of said cavity vacated by the removal of nucleus pulposus tissue.

32. The surgical implant procedure according to claim 31 wherein said xerogel plastic in its anisotropically dehydrated state has the shape optimized for insertion into the cavity through a small incision in the annulus fibrosus, said shape being an approximate shape of a cylindrical body.

33. The surgical implant procedure according to claim 31 wherein said anisotropically dehydrated state is achieved by anisotropical deformation of said xerogel.

34. The surgical implant procedure according to claim 33 wherein said anisotropical deformation is achieved by heating the xerogel above its glass transition temperature, exposing it to deforming stress in a selected direction, and cooling it down under its glass transition temperature while still exposed to said deforming stress.

35. The surgical implant procedure according to claim 33 wherein said anisotropical deformation is achieved by forming said xerogel by drying the hydrated swellable plastic under a restraining stress, preventing shrinking of xerogel in one or more selected directions.

36. The surgical implant procedure according to claim 35 wherein said restraining stress is an external stress caused by applying pressure in axial direction during the dehydration process.

37. The surgical implant procedure according to claim 35 wherein said restraining stress is created by the presence of internally embedded structure preventing the shrinking in the direction lateral to the axis.

38. The surgical implant procedure according to claim 27 wherein said hydrated implant is under axial stress substantially more deformable in axial direction than in lateral direction.

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